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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,784	03/12/2004	Lars Tenerz	030481-0216	5614

22428 7590 11/10/2005

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

NATNITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/798,784	Applicant(s) TENERZ ET AL.	
	Examiner Navin Natnithithadha	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10252005; 07272004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 3, 4, 6, and 7 are objected to because of the following informalities:

The claims recite the term “cavity” or “cavities,” which are not defined in the specification. The specification on page 12 and Figure 12 describe “chambers” 204 and 206. It is not clear as to whether the “cavities” in the claims are in reference to the “chambers” in the specification. The Examiner suggests amending “cavity” and “cavities” in the claims with “chamber(s)”. Appropriate correction is required.

2. Claims 3, 4, 6, 8, and 9 are objected to because of the following informalities:

The claims recite a “cavity” and a “member” in a “wherein” clause. It is not clear as to whether the Applicant intended this limitation to be a structural limitation or a functional limitation. If the Applicant intended this limitation to be a structural element (in regard to the “cavity” and “member” elements), thus providing more patentable weight to an apparatus claim, then the claims should be amended to define the system of claim 1 further comprising the “member” element. If the Applicant intended this limitation to be a functional limitation, then the limitation is a matter of intended use of the subject matter of claim 1, in which the prior art reference would only have to show it is capable of performing the function. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 5, 10-12, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Li, US 6,350,274 B1 (hereinafter referred to as Li).

Claims 1, 11, 16, and 17: Li teaches a system 10 to sense the location of a distal portion of a member within a body (locating the implant member at the wall of the lumen) (see col. 1, line 60 to col. 2, line 18), the system comprising:

an introducer portion (delivery device) 12 having a lumen and distal end (insertable portion) 32 adapted to be placed within a body, the distal end having an opening (outlet) 20 lying in a plane perpendicular to a longitudinal axis of the lumen (see figs. 1 and 2);

a core pin (cylindrical rod-like member) 24 inserted in the introducer portion 12 such that a distal end of the core pin 24 is capable of passing beyond the distal end of the introducer portion (see fig. 5), the core pin 24 having portion of reduced diameter such that a channel (not labeled, see fig. 5) is formed between an inner wall portion 11 of the introducer portion 12 and an outer portion of the core pin 24, the channel having

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an entrance proximal 28 from the distal end of the introducer portion 12 via an opening in the introducer portion 12 (see fig. 5); and

a pressure sensor (pressure monitoring device) 50, fluid communication with the distal end, adapted to provide a pulsation which can be sensed by an operator when the distal end is placed within a pulsating portion of the body (see col. 5, line 51 to col. 6, line 11).

Claim 5: Li teaches the distal end 32 of the introducer portion 12 is adapted to be positionable within a blood vessel 44 (see fig. 2).

Claim 10: Li teaches the pressure sensor comprises a pressure transducer 50/60.

Claim 12: Li teaches the introducer portion further comprises side hole 40 near a distal end 32 of the introducer portion 12 (see fig. 5).

Claims 14 and 15: Li teaches the opening lies a plane perpendicular/parallel to the longitudinal axis of the lumen (see fig. 3).

4. Claims 1, 2, 5, 7, 10, 11, and 13-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al, US 6,302,898 B1 (hereinafter referred to as Edwards).

Claim 1: Edwards teaches a system 10 to sense the location of a distal portion of a member within a body (position sensing mechanism) (see col. 3, lines 10-18), the system comprising:

an introducer portion (sheath) 52 having a lumen 64 and distal end (not labeled) adapted to be placed within a body (see fig. 4b), the distal end having an opening (not

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labeled) lying in a plane perpendicular to a longitudinal axis of the lumen (see figs. 4a and 4b);

a pressure sensor (pressure sensor, not labeled), fluid communication with the distal end 34, adapted to provide a pulsation which can be sensed by an operator when the distal end 34 is placed within a pulsating portion of the body (see col. 7, lines 13-19, and col. 10, lines 1-11).

Claim 2: Edwards teaches the pulsation is visually displayed on a display (position monitor) 40 (see fig. 1a).

Claim 5: Edwards teaches the distal end of the introducer portion is adapted to be positionable within a blood vessel 36 (see fig. 4a).

Claim 7: Edwards teaches the system comprises at least two cavities (closure lumen) 18 and (guidewire lumen) 48 (see fig. 2).

Claim 10: Edwards teaches the pressure sensor comprises a pressure transducer (pressure sensor, not labeled) (see col. 10, lines 1-11).

Claim 11: Edwards teaches a core pin (elongate body) 12 with a channel (lumen, not labeled) (see fig. 1b).

Claims 13-15: Edwards teaches the core pin 12 further comprises an opening 34 at an entrance to the channel (see fig. 4b) and the opening 34 lies a plane perpendicular/parallel to the longitudinal axis of the lumen (see figs. 3b and 4b).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 4, 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al, US 6,302,898 B1 (hereinafter referred to as Edwards).

Claims 3, 4, 6, 8, and 9: Edwards teaches other examples of a position sensing mechanism, which include a pressure port and an electrical contact switch but not limited to these examples. Thus, Edwards would be capable of teaching the "pulsation visually displayed within a cavity," "pulsation causes a member to vibrate such that the vibration of the member can be sensed by touch" and "the pulsation causes a member to vibrate such that the vibration can be visually observed." At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Edwards with the visual display mechanisms of claims 3, 4, 6, 8, and 9 because the Applicant has not disclosed that the claimed visual display mechanism provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the claimed visual display mechanisms because the Edwards technique of using a display is synonymous technique as the ones claimed for providing a visual display of the changing pressure at the tip of the introducer.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-10 are rejected under the judicially created doctrine of obviousness-

type double patenting as being unpatentable over claims 1-5 of U.S. Patent No.

6,682,489 B1. Although the conflicting claims are not identical, they are not patentably

distinct from each other because both the present application and the copending

application claim the same structure of an introducer and an assembly/pressure sensor.

The only difference in the two applications is the function of the assembly/pressure

sensor. The present application claims the pressure sensor senses fluid pulsation in

the body and visually observable at the proximal end; and the copending application

claims an assembly to observe a characteristic of blood at the proximal end. Thus, the

present application is narrower in scope than the copending application.

7. Claims 1 and 11-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/798,438. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present application and the copending application claim the same structure of an introducer, pressure sensor, and/or core pin. The only difference in the two applications is the function of the pressure sensor. The present application claims the pressure sensor senses fluid pulsation in the body; and the copending application claims the pressure senses specifically blood pressure in the body. Thus, the present application is broader in scope than the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

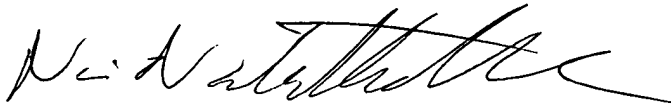
Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Navin Natnithithadha', with a stylized, cursive script.

Navin Natnithithadha
Patent Examiner
GAU 3736
08 November 2005